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Association Between Cervical Ripening Balloon and Stability of Fetal Presentation During Induction of Labor for Live Singleton Pregnancies

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Introduction

- Indications for induction
  - No spontaneous labor after due date
  - Maternal co-morbidities
  - Fetal conditions
- Methods for induction
  - Medication
  - Mechanical
- Concern for increased rate of fetuses rotating from vertex presentation to breech or transverse after balloon placement

Prior Studies

- No studies compare change in fetal presentation between induction methods
- Systematic review in BJOG - adverse effects of balloon[1]
  - 16 studies with 6046 total patients
  - 4 events of malpresentation across 3 studies
  - Rate not compared with non-mechanical methods
- Study of 1083 patients undergoing balloon induction[2]
  - Switch to breech presentation in 14 patients (1.3%)
  - No comparison to other methods
- Other studies have compared prostaglandins versus balloon for time to delivery and rate of vaginal delivery

1. Diederen M, Gommers J, Wilkinson C, Turnbull D, Mol B. Safety of the balloon catheter for cervical ripening in outpatient care: complications during the period from insertion to expulsion of a balloon catheter in the process of labour induction: a systematic review. BJOG. 2018 Aug;125(9):1086-1095.
2. Maslovitz S, Lessing JB, Many A. Complications of trans-cervical Foley catheter for labor induction among 1,083 women. Arch Gynecol Obstet. 2010 Mar;281(3):473-7.

Goal

- Study the previously unaddressed issue of whether balloon induction is associated with higher rate of fetal conversion to malpresentation
- Specifically, we compared the rate of fetal conversion from cephalic presentation to malpresentation in those patients undergoing induction of labor with versus without a cervical ripening balloon

Methods – Study Design

- Retrospective cohort study
- Inclusion criteria:
  - Live, singleton gestations
  - Misoprostol and/or balloon induction of labor
  - One-month study period
- Two cohorts
  - Cervical ripening balloon (with or without misoprostol)
  - Misoprostol alone

Methods – Cervical Ripening Balloon

- Cook catheter
  - 2 balloons inflated to 80mL each.
  - Inner balloon inserted past the internal os
  - Outer balloon in the vaginal canal.
  - Left in place for 12 hours (unless falls out sooner)

Methods – Outcomes and Analysis

- Primary outcome - presentation of fetus at time of delivery
- Secondary outcomes – route of delivery, length of induction
- Additional data collected:
  - Patient age
  - Gravity, parity
  - Weeks of gestation
  - Body mass index (BMI)
  - Ethnicity
  - Diabetic status
  - Prior Cesarean section
  - Estimated fetal weight
  - Cervical exam (dilation, favorable Bishop score)
  - Oligohydramnios, polyhydramnios
  - Membrane status
  - Actual fetal weight

Methods – Statistical analysis

- R statistical software
- Comparison of baseline characteristics and outcomes
  - Continuous variables
    - t-test if values in both groups normally distributed (as determined via Shapiro-Wilk normality test)
    - Wilcoxon rank sum test if non-parametric distribution of values.
  - Categorical variables - Fisher's exact test

Results – Included Patients

- During 30-day study period
  - 52 admissions for induction of labor of live singleton gestations
  - 3 patients excluded - 2 enrolled in a study that used different cervical ripening balloon (different shape/volume of balloon) and 1 patient requested balloon removal immediately after placement
- 49 included patients
  - 36 misoprostol only
  - 13 cervical ripening balloon
    - 2 patients given misoprostol before or after balloon

Results – Baseline Characteristics

Characteristic*	Misoprostol Only (n=36)	Balloon (n=13)	p-value
Age (years)	27.8	31.7	0.099#
Gravity	3.39	3.23	0.88^
Parity	2.06	1.77	0.89^
BMI (kg/m^2)	32.7	31.9	0.49^
Gestation age (weeks)	39.4	39.1	0.68^
Dilation (cm)	1.76	1.30	0.12^
Estimated fetal weight (g)	3355	3197	0.31#
Actual fetal weight (g)	3279	3080	0.19^
Ethnicity	Hispanic: n = 25 White: n = 9 Black: n = 2	Hispanic: n = 13	0.10†

* Mean values reported for continuous variables, number of patients reported for categorical variables

t-test with equal variances

^ Wilcoxon rank sum test

† Fisher's exact test

Results – Baseline Characteristics

Diabetes	GDMA1: n = 4 GDMA2: n = 2 No diabetes: n = 30	GDMA1: n = 1 No diabetes: n = 12	0.99†,**
Prior Cesarean section	None	N = 2	0.066†
Membrane status	Intact: n=33 Ruptured: n=3	Intact: n = 13 Ruptured: n = 0	0.56†
Favorable cervix (Bishop score ≥ 6)	Favorable: n = 7 Unfavorable: n = 19 Unknown: n = 10	Favorable: n = 3 Unfavorable: n = 7 Unknown: n = 3	0.99†
Polyhydramnios	n = 1	n = 0	0.99†
Oligohydramnios	n = 6	n = 2	0.99†

* Mean values reported for continuous variables, number of patients reported for categorical variables

t-test with equal variances

^ Wilcoxon rank sum test

† Fisher's exact test

**p-value 0.66 when re-analyzed as binary outcome (diabetes versus no diabetes)

Results – Primary & Secondary Outcomes

- Primary outcome
  - Change in fetal presentation in 1 of 13 patients in the balloon cohort (6.6%)
  - All stayed vertex in misoprostol-only group
  - No statistical significance (p=0.265)
- Still no statistical significance with analysis adjusted for differences in neonatal weight and amniotic fluid abnormalities (oligohydramnios or polyhydramnios) using multiple logistic regression
- Secondary outcomes
  - Route of delivery: 1/36 Cesarean section in misoprostol group and 3/13 Cesarean section in balloon group (p=0.05)
  - Length of induction: mean 17.5 hours in misoprostol group versus 23.5 hours in balloon group (p=0.06)

Discussion

- Study was unable to demonstrate a statistically significant difference in the rate of fetal conversion to malpresentation during balloon inductions versus inductions without a cervical ripening balloon
- Study severely limited by its restricted sample size
- In prior EMR no systematic method for identifying balloon inductions
  - Required manual review of provider and nursing notes for each patient in the entire labor and delivery census
  - For this study, misoprostol inductions were identified in this same manner to have consistent methods for the two cohorts
- Plan for further study of a larger number of patients with the new EMR
  - Data from a larger set of patients can be reliably obtained
  - Consider prospective cohort study.
  - Suspect a significant difference in rate of conversion of fetal presentation may be identified with a larger sample size.

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